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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,823	CIOK ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-59* is/are pending in the application.

4a) Of the above claim(s) *53-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 37, 39-47, 50 and 52-55, and the species of Fig. 2, claims 37, 39-42, 45-47, 50 and 52 in the reply filed on November 17, 2008 is acknowledged. The traversal is on the ground(s) that the claims share a common inventive concept. This is found persuasive. The restriction and election requirements are withdrawn.

Response to Arguments

2. Applicant's arguments, see Remarks, filed March 11, 2008, with respect to the rejection(s) of claim(s) 37-51 under 35 U.S.C. 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of the previously applied Nielsen reference. Briefly, Nielsen fairly suggests a central part of the second surface of the wafer 7 that is provided with a hydrophobic adhesive layer. Nielsen discloses that the adhesive moldable backing defining the adhesive second surface is made of a material that is a polymer material that protects the second surface of the wafer 7 from stoma secretions. (Page 8, lines 10-13) Nielsen also discloses that the torus is held in its locked position by swelling of the hydrocolloid adhesive from the first surface against both the stoma and the second surface defined by the moldable backing that causes release from the second surface defined by said moldable backing. (Page 8, lines 8-10, Page 12, lines 3-9) It is examiner's position that if the moldable backing adhesive and the second surface defined thereon was hydrophilic, the humidity and secretions disclosed by Nielsen would cause the first surface hydrocolloid adhesive to stick excessively to the moldable backing, interfering with its release from the

second surface and subsequent expansion to properly fit the stoma. Therefore, although Nielsen does not explicitly disclose that the moldable backing adhesive layer defining the second surface is a hydrophobic adhesive layer, Nielsen fairly suggests a hydrophobic adhesive layer as claimed. This ensures that the moldable backing is in fact protecting the wafer from secretions, and is not absorbing moisture in such a manner as to interfere with the expansion of the first surface hydrocolloid adhesive to fit snugly around the stoma.

3. It is noted that although the arguments traversing the restriction and election requirements were persuasive in light of restriction practice with regard to national stage applications, claims 53-59 are still withdrawn from consideration as they are not drawn to the embodiment that has been examined on the merits. This is discussed in detail in paragraph 4 of this Office action.

Election/Restrictions

4. Newly submitted claims 53-59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: In claim 53, a release liner is recited as being covered by the carrier sheet, whereas the second surface is disclosed and claimed as being covered by a carrier sheet in claim 37. Thus it is examiner's position, supported by applicant's disclosure, that the carrier sheet defines the hydrophobic adhesive layer having an upper adhesive surface on the second surface of the wafer. Therefore, an embodiment in which the release liner lies below the carrier sheet lacks the inventive concept shared by the other claims. This is because the recited central part of the second surface can no longer be seen as being provided with a hydrophobic adhesive layer having an upper surface because that hydrophobic layer is separated from that central part of the second surface by the release liner. This hydrophobic adhesive layer provided on the second surface is an essential

part of the inventive concept. Hence, if claims 53-59 were presented originally with claims 37-51, a restriction requirement that would be proper in accordance with 35 U.S.C. 371 practice would have been made.

5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 53-59 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen (WO 98/53771).

With respect to **claim 37:** Nielsen discloses an ostomy appliance body side member 1 comprising an adhesive wafer in the form of a moldable mass of adhesive 7 having an inner rim defining a hole for accommodating a stoma. The wafer 7 is a moldable mass of hydrophilic hydrocolloid adhesive and thus necessarily has a first moisture-absorbing adhesive surface for securing the appliance to a user's skin, as is the nature of a hydrophilic hydrocolloid adhesive. The wafer 5 has a second surface covered with a carrier sheet 16 (Fig. 1, Page 6, lines 19-21) A portion of the adhesive wafer 7 surrounding the stoma, specifically the inner rim, has balanced plastic and elastic properties (Page 11, lines 20-24) A central part of the second surface of said wafer 7 surrounding said stoma-accommodating hole is provided with an adhesive layer in the form of a moldable backing thereon (Figs. 3,7, Page 8, lines 10-14) that is

compatible with the first adhesive surface inasmuch as Nielsen discloses that it is sprayed on the adhesive wafer second surface and it allows the temporary adhesion of the first surface to the second surface 5 shown in Fig. 7. The adhesive layer/moldable backing has an adhesive upper surface that allows the hole to be enlarged by rolling up the inner rim to form a torus 20. (Fig. 7, Page 12, lines 3-6) The torus 20 is locked in said rolled up position by adhesion between the first hydrocolloid adhesive surface that has swelled upon absorption of moisture, and said adhesive upper surface of the moldable backing as provided on said second surface.

Nielsen discloses that the adhesive moldable backing defining the adhesive second surface is made of a material that is a polymer material that protects the second surface of the wafer 7 from stoma secretions. (Page 8, lines 10-13) Nielsen also discloses that the torus is held in its locked position by swelling of the hydrocolloid adhesive from the first surface against both the stoma and the second surface defined by the moldable backing that causes release from the second surface defined by said moldable backing. (Page 8, lines 8-10, Page 12, lines 3-9) It is examiner's position that if the moldable backing adhesive and the second surface defined thereon was hydrophilic, the humidity and secretions disclosed by Nielsen would cause the first surface hydrocolloid adhesive to stick excessively to the moldable backing, interfering with its release from the second surface and subsequent expansion to properly fit the stoma. Therefore, although Nielsen does not explicitly disclose that the moldable backing adhesive layer defining the second surface is a hydrophobic adhesive layer, it would be obvious to one of ordinary skill in the art to modify the device of Nielsen such that the moldable backing adhesive layer provided on the second surface of the wafer is a hydrophobic adhesive layer. This ensures that the moldable backing is in fact protecting the wafer from secretions, and is not absorbing moisture in such a manner as to interfere with the expansion of the first surface hydrocolloid adhesive to fit snugly around the stoma. The device fairly suggested by Nielsen thus renders

the limitation "the torus being locked in said rolled up position by adhesion between the first adhesive surface and said adhesive upper surface of the hydrophobic adhesive layer as provided on said second surface" obvious.

With respect to **claim 39:** Adhesive wafer 7 disclosed by Nielsen is made from an adhesive including hydrocolloids. (Page 8, lines 8-10)

With respect to **claim 40:** As can be seen in Fig. 1, the carrier sheet 16 is absent on a central part of the second surface surrounding the stoma.

With respect to **claim 41:** The hydrophobic adhesive of the moldable backing suggested by Nielsen stretches under at least a portion of the carrier sheet 16. (Fig. 1) The motivation to modify the device of Nielsen so as to have a moldable backing that is a hydrophobic adhesive layer defining a second surface is stated *supra* with respect to claim 37.

With respect to **claim 42:** A release liner 15 disclosed by Nielsen protects the first adhesive surface. (Fig. 1, Page 6, lines 9, 10)

With respect to **claim 43:** The carrier sheet 16 disclosed by Nielsen extends to the central part of the wafer 7. (Fig. 1)

With respect to **claim 44:** The carrier sheet 16 on a central part of the second surface of the adhesive wafer 7 surrounding the stoma is provided with a weakening pattern in the form of a slit liner in the area defining handle 17. (Page 6, lines 23-25)

With respect to **claim 45:** The part of the adhesive wafer 7 surrounding the stoma is formed as an exchangeable sealing member associated with a receiving member 4 and is disposed in a hole of the wafer and having a hole for accommodating a stoma. (Page 7, lines 15-18)

With respect to **claim 46:** Body side member 1 further comprises a coupling component 18 for releasable attachment of a receiving bag 4. (Page 8, line 22)

With respect to **claim 47:** The coupling component disclosed by Nielsen includes matching coupling rings 18. (Page 8, line 22)

With respect to **claim 48:** Nielsen discloses an ostomy sealing member in the form of bodyside member 1 that is in the form of a mouldable mass or ring 7 having balanced plastic and elastic properties comprising a first adhesive surface to adhere to the skin and to seal around a stoma and between the stoma. The sealing member 1 also comprises an ostomy appliance in the form of receiving member 4 attached thereto and adapted to receive secretions from the stoma, a second surface facing away from the user and an inner rim defining a hole 3 for accommodating the stoma. (Fig. 1, Page 6, lines 8-19) The sealing member 1 is configured, via mass 7 having said balanced elastic and plastic properties, to allow enlargement of said stoma-accommodating hole 3 by rolling up the inner rim of the hole to form a torus 20 before placing the sealing member around the stoma. (Fig. 7, Page 8, lines 4-7) A part of the second surface surrounding the hole has a separate adhesive layer thereon in the form of a moldable backing which is different from and compatible with the first adhesive surface inasmuch as Nielsen discloses that it is sprayed on the adhesive wafer second surface and it allows the temporary adhesion of the

first surface to the second surface shown in Fig. 7. The separate moldable backing/adhesive layer disclosed by Nielsen has an adhesive upper surface to lock the torus 20 in said rolled up position by adhesion between the first adhesive surface and said adhesive upper surface of the hydrophobic adhesive layer even when said first adhesive surface is exposed to moisture.

Nielsen discloses that the adhesive moldable backing defining the adhesive second surface is made of a material that is a polymer material that protects the second surface of the wafer 7 from stoma secretions. (Page 8, lines 10-13) Nielsen also discloses that the torus is held in its locked position by swelling of the hydrocolloid adhesive from the first surface against both the stoma and the second surface defined by the moldable backing that causes release from the second surface defined by said moldable backing. (Page 8, lines 8-10, Page 12, lines 3-9) It is examiner's position that if the moldable backing adhesive and the second surface defined thereon was hydrophilic, the humidity and secretions disclosed by Nielsen would cause the first surface hydrocolloid adhesive to stick excessively to the moldable backing, interfering with its release from the second surface and subsequent expansion to properly fit the stoma. Therefore, although Nielsen does not explicitly disclose that the moldable backing adhesive layer defining the second surface is a hydrophobic adhesive layer, it would be obvious to one of ordinary skill in the art to modify the device of Nielsen such that the moldable backing adhesive layer provided on the second surface of the wafer is a hydrophobic adhesive layer. This ensures that the moldable backing is in fact protecting the wafer from secretions, and is not absorbing moisture in such a manner as to interfere with the expansion of the first surface hydrocolloid adhesive to fit snugly around the stoma. The device fairly suggested by Nielsen thus renders the limitation "to lock the torus in said rolled up position by adhesion between the first adhesive surface and said adhesive upper surface of the hydrophobic adhesive layer even when said first adhesive surface is exposed to moisture" obvious.

With respect to **claim 49:** Sealing member 7 is made from an adhesive including hydrocolloids. (Page 8, lines 8-10)

With respect to **claim 50:** Nielsen teaches a method of applying an ostomy appliance body side member having an adhesive wafer 2 with an inner rim that defines a hole 3 for accommodating a stoma, a first adhesive surface for securing the appliance to a user's skin and a second surface covered with a carrier sheet 16, a portion of the adhesive wafer surrounding the stoma having balanced plastic and elastic properties. A central part of the second surface surrounding said stoma-accommodating hole is provided with an adhesive in the form of a moldable backing/adhesive layer that is compatible with the first adhesive surface of the adhesive wafer inasmuch as Nielsen discloses that it is sprayed on the adhesive wafer second surface and it allows the temporary adhesion of the first surface to the second surface shown in Fig. 7. The method disclosed by Nielsen comprises the following steps: a) enlarging the hole to the size of the stoma by rolling the inner rim of the hole of the sealing member forming a torus 20 (Page 12, lines 3-13); b) locking the torus 20 to the second surface of the sealing member 7 in its rolled position by contact between the hydrophobic adhesive of member 7 and the first adhesive surface (Page 12, lines 14-17); and c) aligning the stoma and the stoma-accommodating hole of the ostomy appliance body side member 1 (Page 12, lines 10-13) and placing the body side member on the abdomen of the ostomate with the stoma projecting into the hole, creating a snug fit between the appliance and the ostomy. (Page 12, lines 10-13)

Nielsen discloses that the adhesive moldable backing defining the adhesive second surface is made of a material that is a polymer material that protects the second surface of the wafer 7 from stoma secretions. (Page 8, lines 10-13) Nielsen also discloses that the torus is

held in its locked position by swelling of the hydrocolloid adhesive from the first surface against both the stoma and the second surface defined by the moldable backing that causes release from the second surface defined by said moldable backing. (Page 8, lines 8-10, Page 12, lines 3-9) It is examiner's position that if the moldable backing adhesive and the second surface defined thereon was hydrophilic, the humidity and secretions disclosed by Nielsen would cause the first surface hydrocolloid adhesive to stick excessively to the moldable backing, interfering with its release from the second surface and subsequent expansion to properly fit the stoma. Therefore, although Nielsen does not explicitly disclose that the moldable backing adhesive layer defining the second surface is a hydrophobic adhesive layer, it would be obvious to one of ordinary skill in the art to modify the device of Nielsen such that the moldable backing adhesive layer provided on the second surface of the wafer is a hydrophobic adhesive layer. This ensures that the moldable backing is in fact protecting the wafer from secretions, and is not absorbing moisture in such a manner as to interfere with the expansion of the first surface hydrocolloid adhesive to fit snugly around the stoma. The device fairly suggested by Nielsen thus renders the limitation "a central part of the second surface surrounding said stoma-accommodating hole being provided with a hydrophobic adhesive compatible with the first adhesive surface of the adhesive wafer" obvious.

With respect to **claim 51:** Nielsen teaches a method of applying a separately exchangeable ostomy sealing member 2 in a body side member 1, said sealing member having balanced plastic and elastic properties and including an inner rim that defines a first hole 3 for accommodating a stoma, a first adhesive surface adapted for securing the sealing member to a user's skin and for receiving secretions from the stoma, and a second surface facing away from the user. A central part of the second surface surrounding said stoma-accommodating hole is

provided with an adhesive in the form of a moldable backing/adhesive layer that is compatible with the first adhesive surface of the adhesive wafer inasmuch as Nielsen discloses that it is sprayed on the adhesive wafer second surface and it allows the temporary adhesion of the first surface to the second surface shown in Fig. 7. The method disclosed by Nielsen comprises the following steps: a) locating the stoma and aligning the stoma and the hole of the body side member and placing the body side member on the abdomen of the ostomate with the stoma projecting into the hole (Page 11, line 25 – Page 12, line 3), b) enlarging the hole of the sealing member by rolling the inner rim of the hole of the sealing member forming a torus 20 (Page 12, lines 3-6), c) adapting the hole to the size of the stoma (Page 12, lines 10-13), d) locking the torus 20 to the second surface of the sealing member 7 in its rolled position by contact between the adhesive surface and the second surface of the sealing member (Page 12, lines 14-17), e) aligning the stoma and the second hole of the ostomy sealing member (Page 12, lines 10-13) and f) placing the sealing member 7 in the second hole of the body side member on the abdomen of the ostomate with the stoma projecting into the first hole 3, creating a snug fit between the appliance and the ostomy. (Fig. 1, Page 12, lines 10-13)

Nielsen discloses that the adhesive moldable backing defining the adhesive second surface is made of a material that is a polymer material that protects the second surface of the wafer 7 from stoma secretions. (Page 8, lines 10-13) Nielsen also discloses that the torus is held in its locked position by swelling of the hydrocolloid adhesive from the first surface against both the stoma and the second surface defined by the moldable backing that causes release from the second surface defined by said moldable backing. (Page 8, lines 8-10, Page 12, lines 3-9) It is examiner's position that if the moldable backing adhesive and the second surface defined thereon was hydrophilic, the humidity and secretions disclosed by Nielsen would cause the first surface hydrocolloid adhesive to stick excessively to the moldable backing, interfering

with its release from the second surface and subsequent expansion to properly fit the stoma. Therefore, although Nielsen does not explicitly disclose that the moldable backing adhesive layer defining the second surface is a hydrophobic adhesive layer, it would be obvious to one of ordinary skill in the art to modify the device of Nielsen such that the moldable backing adhesive layer provided on the second surface of the wafer is a hydrophobic adhesive layer. This ensures that the moldable backing is in fact protecting the wafer from secretions, and is not absorbing moisture in such a manner as to interfere with the expansion of the first surface hydrocolloid adhesive to fit snugly around the stoma. The device fairly suggested by Nielsen thus renders the limitation "a central part of the second surface surrounding said stoma-accommodating hole being provided with a hydrophobic adhesive compatible with the first adhesive surface of the adhesive wafer" obvious.

With respect to **claim 52:** A release liner in the form of a protective film as part of said moldable backing protects the adhesive upper surface of said hydrophobic adhesive layer. The release liner is necessarily removed prior to forming said torus, as formation of the torus requires access to the upper adhesive layer to temporarily hold the inner rim in its rolled position prior to formation, release and lock of the torus 20 against the stoma. Thus if the torus is formed, the release liner has already been removed. (Page 7, lines 1-9)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761